REMARKS

Claims 1-40 are canceled without prejudice or disclaimer. Claims 41-62 are added.

New claims 41-62 replace claims 22-40. The new claims present the elected subject matter. The new claims recite that the mutation is in a gene encoding a polypeptide having at least 95% identity to SEQ ID NO:2. The new claims also recite that the gene is native to the *B. licheniformis* host. Support for the new claims is found in the specification at page 1, lines 30-37 and page 4, lines 15-19.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

I. The Rejection of Claims 22-40 under 35 U.S.C. 112 (Written Description)

Claims 22-40 are rejected under 35 U.S.C. 112, first paragraph, as allegedly lacking adequate written description. New claims 41-62 are presented. Applicants address the rejection as applied to the new claims.

The written description requirement of the Patent Code is fulfilled when the patent specification describes the claimed invention in sufficient detail such that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. *See* Vas-Cath, Inc. v. Mahurkar, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). The written description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. *See* In re Marzocchi, 169 USPQ 367 (CCPA 1971).

The present invention is directed to mutant B. *licheniformis* host cells in which certain genes have been identified as encoding proteins involved in antibiotic synthesis in a B. *licheniformis* host, the mutation of which can improve the B. *licheniformis* host cell for use in the production of polypeptides, amino acids, carbohydrates, etc. In particular, the new claims claim a mutant B. *licheniformis* host cells in which a gene encoding a polypeptide having at least 95% identity to SEQ ID NO:2 has been mutated, which results in the mutant B. *licheniformis* host cell expressing a lower amount of the polypeptide. See the specification at page 3, lines 31-37.

The Examiner alleges that the specification lacks written description support for a mutant B. *licheniformis* host cells in which one or more genes encoding polypeptides having at least 80% identity to SEQ ID NO:2 have been mutated. The Examiner states that Applicants' specification fails to show that Applicants were in possession of the claimed genus.

It is respectfully submitted that the specification provides written description support for the claimed invention. The specification discloses that the mutation of a gene encoding the polypeptide of SEQ ID NO:2 and highly homologous genes encoding polypeptides having at least 95% identity to SEQ ID NO:2 will result in improved B. *licheniformis* host cells. See the specification at page 1, lines 25 to page 2, line 9. Based on this disclosure, an artisan would reasonably conclude that Applicants were in possession of not only mutant B. *licheniformis* host cells with a mutation in the gene encoding the polypeptide of SEQ ID NO:2, but also mutant B. *licheniformis* host cells with a mutation in highly homologous genes as covered by the claims. In fact, it is well known in the art that there are many strains of B. *licheniformis*, and these strains are known to differ genetically from each other. *See, e.g.*, De Clerck and De Vos, "Genotypic Diversity among Bacillus licheniformis strains from various sources", FEMS Micbiol. Letters, 231, 91-98 (2004) (see Table 1). Accordingly, the claims encompass such known natural variation in B. *licheniformis* strains by reciting a degree of identity of at least 95%. An artisan would reasonably conclude that Applicants were in possession of not only B. *licheniformis* hosts having a gene encoding SEQ ID NO:2, but also other B. *licheniformis* strains encoding highly homologous genes, as encompassed by the claims. The claims have also been amended to recite that the mutated gene is native to the *B. licheniformis* host.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

II. The Rejection of Claims 22-40 under 35 U.S.C. 112 (Enablement)

Claims 22-40 are rejected under 35 U.S.C. 112 as allegedly lacking enablement. New claims 41-63 are presented. Applicants address the rejection as applied to the new claims. The Examiner alleges that the specification is not considered enabling for mutation of a gene in a B. *licheniformis* host which is at least 80% identical to SEQ ID NO:2 given the unpredictability between sequence, structure and function.

The specification discloses mutant B. *licheniformis* host cells in which the mutation of a gene encoding the polypeptide comprising an amino acid sequence shown as SEQ ID NO:2 and genes encoding homologous polypeptides having at least 80%, 85%, 90%, 95% and 97% identity to SEQ ID NO:2 will result in an improved host cell that expresses a lower amount of a polypeptide involved in antibiotic synthesis. See the specification at page 1, lines 25 to page 2, line 9. As amended, the claims recite a degree of identity of at least 95% to SEQ ID NO:2. Based on the high identity, an artisan can reasonably expect that the mutation of genes encoding polypeptides having

at least 95% identity to SEQ ID NO:2 would have a similar effect as a mutation of the gene encoding SEQ ID NO:2 as it is highly predicted that such genes would encode proteins with a similar structure and function to the protein having the amino acid sequence of SEQ ID NO:2. This is evidenced by the scientific publication by B. Rost, "Twilight Zone of Protein Sequence Alignments," Prot. Eng, Vol 12, no. 2, pp.85-94 (1999) (see, e.g., Figure 4) and B. Rost et al., "Automatic Prediction of Protein Function," CMLS, 60, pp. 2637-2650 (2003) (see, e.g., Figure 1) which discuss the predictability in structure and function based on highly sequence identity/homology. In the present case, the percentage of identity of 95% is extremely high and the predictability that genes encoding such sequences in B. *licheniformis* host will have the same structure and function is also extremely high. Moreover, given the high level of skill in the art, the artisan is enabled to mutate such highly homologous genes in B. *licheniformis* hosts with a reasonable expectation that a similar result will occur. The tasks required to carry this out are routine in the art. Indeed, one skilled in the art would have a very high degree of predictability of being able to practice the claimed invention in B. *licheniformis* host strains in general for both the gene encoding SEQ ID NO:2 and highly related genes.

Accordingly, for the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

III. The Rejection of Claim 23 under 35 U.S.C. 112 (Indefiniteness)

Claim 23 is rejected under 35 U.S.C. 112 as indefinite for the recitation "mutated by a partial or complete deletion of one or more genes." The new claims render this rejection moot.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

IV. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

Date: January 22, 2007

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